SECTION 5: 510(K) SUMMARY

MAR 19 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

Submitter	MEMOMETAL TECHNOLOGIES Campus de Ker Lann - Rue Blaise Pascal 35170 BRUZ – France Phone : + 33 (0)2 99 05 50 66 Fax :+ 33 (0)2 99 05 95 62
Contacts	Gilles AUDIC Quality Manager Bernard PRANDI General Manager e-mail: info@memometal.com
Preparation date	December 15, 2006
Trade Name	MEMOMETAL varisation staples (AV XX-YY)
Common Name	Varisation staples
Classification Name	Staples, Fixation, Bone
Legally marketed predicate devices	(DEPUY Inc) varisation staple
Description	MEMOMETAL varisation staple is a staple with two self drilling tips. The treatment with a varisation staple allows, after possible treatment of the second ray, to correct the valgus deformation of the first ray and to recreate a square or Greek foot. Two types of staples are available depending on the bone surface
Intended Use	The MEMOMETAL varisation staple is intended to be implanted for fixation of small bone fractures or for small bone reconstruction.
Indication for use	- The MEMOMETAL varisation staple is indicated for Akin type osteotomy.
Performance data	The MEMOMETAL varisation staple is conform to ASTM F564-02 Standard Specification and Test Methods for Metallic Bone staples and to ISO 5832-1 Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-

	1:1997).
Substantial equivalence	THE MEMOMETAL varisation staples are substantially equivalent to their predicate devices Depuy .inc varisation staples in terms of intended use and indications for use, material, design and function. Any minor differences between these two devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Memometal Technologies
% Gilles Audic
Quality Manager
Rue Blaise Pascal
Campus De Kerr Lann
Bruz, France F35170

MAR 19 2007

Re: K070033
Trade/Device Name: Memometal Varization Staples
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: December 19, 2006
Received: January 03, 2007

Dear Mr. Audic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Barbara Burkhart for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: MEMOMETAL VARISATION

Indications for Use:

- The MEMOMETAL varisation staples (AV XX-YY) are indicated for Akin type osteotomies

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler

(Division Sign-Off)
Division of General Restorative, and Neurological Devices

510(k) Number K070033